K112178

OCT 27 2011

510(k) Summary

Preparation Date: October 24, 2011

Manufacturer and contact Information

Manufacturer:

JMS Singapore Pte Ltd
440, Ang Mo Kio Industrial Park 1
Singapore 569620

Sponsor:

JMS North America Corporation
22320 Foothill Blvd., Suite 350
Hayward, CA 94541
USA

Contact Information for Sponsor:

Mr Sho Hosoki
Coordinator of Product Management and Regulatory Affairs
JMS North America Corporation
22320 Foothill Blvd., Suite 350
Hayward, CA 94541
Email: SHosoki@jmsna.net
Telephone: (510) 888-9090
Fax: (510) 888-9099

1. **Trade Name:**

JMS Apheresis Needle Set "WingEater®"

JMS North America Corp will continue to name the new modified device as "JMS Apheresis Needle Set "WingEater®". For the purpose

of this submission, we will refer our predicate and new modified device as:

Predicate device	JMS Apheresis Needle Set "WingEater®" V1
New modified device	JMS Apheresis Needle Set "WingEater®" V2

2. Device Classification Name

Gastroenterology Devices Panel has classified modified device of JMS Apheresis Needle Set "WingEater®" V2 (21 CFR 876.5540) as Class II.

3. Predicate Device Name

Predicate device used in this submission is JMS Apheresis Needle Set "Wing Eater®" V1, (510(k) number - K010410, cleared on 20 June 2001).

4. Device Intended use

Use for providing access to a donor's blood for apheresis. This device is intended to single use only and is for temporary catheterization less than 30 days. The safety feature (foldable wing and WingEater) aids in prevention of needlestick injuries when removing and discarding needle after blood collection.

5. Device Description

JMS Apheresis Needle Set "WingEater®" V2 is a device whereby an anti-needlestick feature (WingEater guard) is assembled with predicate device under 510(k), K00845.

Needlestick injury can be prevented by pulling the PVC tube to retract the needle and wing into WingEater guard when removing needle so as to encapsulate the whole needle within the WingEater guard.

Modifications to JMS Apheresis Needle Set "WingEater®" V2 in this special 510(k) are:

a) Additional new polypropylene (PP) materials used for WingEater guard, needle cover, luer lock cover and clamp (non fluid pathway)

There are other non-significant changes which were made to 510(k) - K010410 in the past. These changes are listed under Attachment 004_List of Past Changes of this special 510(k).

Evaluation of the new packaging configuration was performed accordingly to stimulated conditions experienced during transportation. New design and material used for the WingEater guard was evaluated accordingly with folded wing in order to realize the actual device usage. Reviews of the modifications were documented within this special 510(k) submission.

6. Technological Characteristics and Substantial Equivalence

JMS Apheresis Needle Set "WingEater®" V2 has same intended use and identical fundamental scientific technology as JMS Apheresis Needle Set "WingEater®" V1. Bench testing had been conducted to verify performance of JMS Apheresis Needle Set "WingEater®" V2 and it was found to be safe and effective. The following data and reports were enclosed within this submission document.

- ISO 10993-4:2002 Biological Evaluation of Medical Devices – Part 4 – Selection of Tests for Interactions with Blood
- ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5 – Tests for In Vitro Cytotoxicity
- ISO 10993-10 Biological Evaluation of Medical Devices – Part 10 – Tests for Irritation and Delayed-Type Hypersensitivity

- ISO 10993-11 Biological Evaluation of Medical Devices – Part 11 – Tests for Systemic Toxicity
- ISO 594-1: 1986 Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1 – General Requirements
- ISO 594-2: 1998 Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2 – General Requirements
- ISO 1135-4 4th Edition 2010-04-15, Transfusion Equipment for Medical Use _ Part 4 – Transfusion Sets for Single Use
- ISO 11135-1:2007 Sterilization of Health Care Products – Ethylene Oxide – Part 1 – Requirements for Development, Validation and routine control of a sterilization process for medical devices. (Sterility)
- ISO 11137-1 Sterilization of Health Care Products – Radiation – Part 1 – Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices. (Sterility)
- ISO 11137-2:2006 Sterilization of Health Care Products – Radiation – Part 2 – Establishing the Sterilization Dose
- ISO 11137-3:2006 2010 Sterilization of Health Care Products – Radiation – Part 3 – Guidance on Dosimetric Aspects
- ISO 11607-1:2007 Packaging for Terminally Sterilized Medical Devices – Part 1: Requirements for Materials
- ISO 11607-2: 2006 Packaging for Terminally Sterilized Medical Devices – Part 2: Validation Requirements for Forming, Sealing and Assembly Processes
- ISO 14644-1: 1999 Clean rooms and associated controlled environments- Part 1: Classification of air cleanliness
- ISO 14644-2: 2000 Clean rooms and associated controlled environments -- Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1

- ISO 9626: 1991 + (Amd1:2001) Stainless Steel Needle Tubing for the Manufacture of Medical Devices
- USP 32:2009 <71> Sterility Tests
- USP 33:2010 <85> Bacterial Endotoxins
- ISO 14971:2007 Medical Devices – Application of Risk Management to Medical Devices

Thus, the information provided in this submission clearly demonstrated Substantial Equivalence of JMS Apheresis Needle Set "WingEater®" V2 to the predicate device JMS Apheresis Needle Set "WingEater®" V1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 7 2011

Mr. E.J. Smith
Consultant
JMS North America Corporation
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K112178
Trade/Device Name: JMS Apheresis Needle Set "WingEater®"
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: FIE, FOZ
Dated: September 29, 2011
Received: September 30, 2011

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number: K112178

Device Name: Needle, Fistula

Indications For Use: Use for providing access to a donor's blood for apheresis. This device is intended to single use only and is for temporary catheterization less than 30 days. The safety feature (foldable wing and WingEater) aids in prevention of needlestick injuries when removing and discarding needle after blood collection.

Prescription Use ____√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ACTING FOR RICHARD CHAPMAN.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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